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| EXAMINER |
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NGUYEN, TUAN VAN

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| ART UNIT | PAPER NUMBER |
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3731

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| NOTIFICATION DATE | DELIVERY MODE |
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03/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/615,625 | Applicant(s) COOK ET AL. | |
| | Examiner TUAN V. NGUYEN | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In previous Office action, claims 1-19 and 21-25 were pending. Claims 1-19 and 21-25 were examined and rejected.

Reopening of Prosecution After Appeal

2. In view of the appeal brief filed on December 8, 2008, PROSECUTION IS
HEREBY REOPENED. A new ground of rejection is set forth below:

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or, (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Response to Arguments

3. Applicant's arguments in the appeal brief with respect to the rejection of claim 19 under 35 U.S.C. 102 have been fully considered but they are not persuasive.

Examiner contends that with respect to the recited structure limitations of the anchor, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961).

4. Applicant's arguments in the appeal brief with respect to the rejection of all claims under 35 U.S.C. 103 have been fully considered but they are not persuasive for the reason set forth in detail rejection below.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Donnelly et al. (U.S. 6,773,436).**
7. Donnelly et al discloses (Figs. 9A-9D and col. 8, lines 16-65) a method of attaching tissue to a bone in a patient's body comprising the step of: providing suture anchor; forming a bone cavity (Fig. 9B); securing the suture strand to a

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- portion of tissue to be attached to bone (Fig. 9C); inserting the suture anchor into the bone cavity and toggling the suture anchor by pulling the suture (Fig. 9D).
8. With respect to the recited structure limitations of the anchor, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).
9. **Claims 1, 8, 9-13, 15, 16 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Haut et al. (US 7320701).**
10. Haut discloses (see Figs. 1, 2 and 5-6) a bioabsorbable suture anchor 100 for anchoring tissue to a bone, comprising: an elongate body defined by a longitudinal axis; a first, leading end 120, and a second, trailing end; the elongate body comprising two opposed surfaces (see Fig. 2) between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces (see Fig. 2); a flared portion 115, includes biting edge formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 110, that includes rounded edge on both sides, formed in the elongate body for passage of a suture strand 340a or 340b therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 1); wherein the suture anchor is configured to toggle and anchor inside a bone cavity by the suture (col. 5, line 12 to col. 6, line 35); and the anchor also includes a

portion located at the proximal end for engaging with insertion tool (see col. 4, lines 35-48), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 4, lines 35-48).

11. Referring to claim 19, Haut also discloses the method of deployment the anchor into a bone hole as claimed by the applicant (col. 5, line 12 to col. 6, line 35).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 2, 3, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as unpatentable over Haut et al. (US 7320701).**

15. Noting that Haut discloses the size of suture anchor is approximately 10.5 mm and the width is approximately 3.5 mm (see col. 4, lines 28-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Cassidy (U.S. 6,280,474) discloses a bone anchor can be used to attached small bone to small bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65).
16. Referring to **claim 14**, Haut discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer such as stainless steel (see col. 4, lines 5-15). It is old and well known in the art that polymer and stainless steel has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the surgery or by X-ray after the surgery (Stainless steel exhibits radiopaque property) for the indication of the location of the anchor in the surgical site. It is old and well known that color such as yellow, red, and blue enhancing the ability of visual recognition to the human eye. Therefore, it would have been obvious to one of ordinary skill in the art to use blue dye to cover the nature color of the stainless

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steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer.

Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color of Haut device, and applicant's invention, to perform equally well.

17. **Claims 1-5 and 8-18 are rejected under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. (U.S. 6,270,518) in view of Barlett (US 5,626,612).**
18. Pedlick discloses (see Figs. 35-36 and 38-41) a bioabsorbable suture anchor 301 for anchoring tissue to a bone, comprising: an elongate body 310 defined by a longitudinal axis; a first, leading end 302, includes a rounded distal end 304, and a second, trailing end 306; the elongate body comprising two opposed surfaces 320 between the first and second ends, and a plurality of sidewalls 312, 316 extending between the two opposed surfaces; a flared portion 308, includes biting edge 322 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and a suture channel 330, that includes rounded edge 330 on both sides, formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 41); and the anchor also includes a blind hole 334 for

engaging with insertion tool (see Fig. 36), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 14, lines 1–60).

19. The device of Pedlick discloses the invention substantially as claimed except for suture channel is laterally offset from the longitudinal axis of the anchor in a direction opposite the direction of the flared portion. Noting that Pedlick discloses the suture opening or channel 5 of embodiment as shown in Fig. 1 is offset from the center of the anchor for the purpose of toggling the anchor (col. 8, line 68 to col. 9, line 4) and Bartlett discloses (Fig. 7 and col. 8, lines 53-65) suture anchor comprising, among other things, a suture channel 36 that is laterally offset from the longitudinal axis of the anchor. Apparently, the advantage of the suture bore located laterally offset from the centerline of the anchor is for preventing detrimentally effecting the strength of the suture anchor. It has been held that substitution one known element for another to obtain predictable results is old and well known in the art, therefore, it would have been obvious to substitute the hole of Pedlick anchoring device as shown in Fig. 35 with the hole as disclosed by Bartlett wherein the hole is offset from the center of the anchor for the purpose of toggling the anchor and preventing detrimentally effecting the strength of the suture anchor.
20. Further, applicant has not disclosed that the suture channel that is laterally offset from the longitudinal axis of the body provides an advantage, or solves a stated problem. It would have been obvious matter of design choice to one of ordinary

skill in the art to make the suture channel of Pedlick according to the claimed invention. One of ordinary skill in the art, furthermore, would have expected the suture channel of Bartlett device, Pedlick device, and applicant's invention, to perform equally well.

21. Referring to **claims 2, 3, 14, 15, 17, and 18**, noting that Pedlick discloses the diameter size of suture anchor is 3 mm and the suture anchor having an overall size smaller than conventional bone anchors (see col. 9, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design a suture anchor having elongate body is in the range of about 2-6 mm and the width of the anchor is about 1 mm to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Cassidy (U.S. 6,280,474) discloses a bone anchor can be used to attached small bone to small bone or soft tissue to bone (see Figures 11B and 6B and col. 3, lines 29-38) wherein the overall dimensions of the anchor is 1 mm to about 6 mm wide and between 3 mm to 30 mm long (see col. 3, lines 62-65).
22. Referring to **claim 14**, Pedlick discloses the suture anchor may be made of bioabsorbable or non-bioabsorbable polymer such as stainless steel (see col. 10, lines 45-61). It is old and well known in the art that polymer and stainless steel has its own natural color. The natural color of the material that made the suture anchor can be used as visual indication by the naked eyes of the surgeons during the

surgery or by X-ray after the surgery (Stainless steel exhibits radiopaque property) for the indication of the location of the anchor in the surgical site. It is old and well known that color such as yellow, red, and blue enhancing the ability of visual recognition to the human eye. Therefore, it would have been obvious to one of ordinary skill in the art to use blue dye to cover the nature color of the stainless steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer. Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color of Donnelly et al device, and applicant's invention, to perform equally well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/25/09